

**REMARKS**

The claims remain rejected under 35 U.S.C. §103(a) over Cook (U.S. Pat. No. 5,554,646) and Cook (U.S. Pat. No. 5,428,072) in view of Chin *et al.* Applicants believe the claims are in condition for allowance for the following reasons.

First, as a preliminary matter, Applicants respectfully submit that the Examiner has failed to be responsive to the extensive arguments presented in the Amendment dated March 28, 2001 and has chosen instead to reply only to selected arguments and repeat arguments that were previously made. The Examiner must respond to all of the arguments and evidence presented by Applicants. The MPEP states that:

**Office personnel should consider all rebuttal arguments and evidence presented by applicants.** . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . **Office personnel should avoid giving evidence no weight**, except in rare circumstances. *Id.* See also *In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

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A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. See, e.g., *Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. See, e.g., *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.<sup>1</sup>

Additionally, the Courts have held as follows:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over . . . . An earlier decision should not . . . be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only its knockdown ability. Analytical fixation on an earlier decision can tend to provide the decision with an undeservedly broadened umbrella effect. *Prima facie* obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.<sup>2</sup>

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<sup>1</sup> MPEP §§2144.08; emphasis added).

<sup>2</sup> *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976).

Furthermore:

If a *prima facie* case is made in the first instance, and if the applicant comes forward with a reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.<sup>3</sup>

Accordingly, even if the Examiner had established a *prima facie* of obviousness in the preceding office action (and Applicants contend that he did not), the Examiner must respond to Applicants arguments. In particular, the Examiner has not responded to the arguments on pages 5-8 of the 3/28/01 Amendment that the Cook *et al.* patents do not teach the compositions of the present invention because they do not provide a method for making the compositions and provide absolutely no data on their compositions and has not responded to the claim-by-claim arguments on pages 9-10 of the 3/28/01 Amendment. Applicants request that these arguments be reconsidered in conjunction with Applicants response to the current office action below.

The Applicants repeat that the Examiner has not established a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP § 2143). Failure to establish **any one** of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims in issue.<sup>4</sup> The Examiner has failed to provide references that teach each element of the claims and has failed to provide references that provide a reasonable expectation of success.

As described above, the Examiner has failed to reply to Applicants' extensive arguments that the cited references do not teach each element of the claims. Instead of responding to these arguments, the Examiner states that "[n]ote, question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of

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<sup>3</sup> *In re Hedges*, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986).

<sup>4</sup> *See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must [sic] considered. *In re Lamberti and Konert* (CCPA), 192 USPQ 278)."<sup>5</sup> Applicants respectfully submit that this statement made by the courts cannot be taken out of context. The cited case involved claims to asymmetric dialkyl moieties. The prior art did not expressly disclose these compounds, but did suggest such compounds by referencing at least one methylene group attached to the sulfur atom. This set of facts is completely different from the present case where it is being argued that the cited references do not teach how to make the compositions of the present invention and thus cannot provide each element of the claims.

Viewed in another way, in order to render a claimed apparatus or method obvious under Section 103, the prior art must enable one skilled in the art to make and use the apparatus or method.<sup>6</sup> The cited references do not provide each element of the claims because they do not enable a method of making the claimed compositions. Furthermore:

A claimed chemical compound is *prima facie* obvious only if there is "prior art close enough to the claimed invention to give one skilled in the relevant art the motivation to make close relatives (homologs, analogs, isomers, etc.) of the prior art compound(s)."<sup>7</sup>

The cited prior art provides **no method** capable of producing the claimed compositions.

The Examiner attempts to argue that "applicants conclusion that Cook would produce large amount of unwanted isomers is not convincing because the conclusion is based on result from a similar method, not from the method of Cook."<sup>8</sup> This statement completely ignores Applicants extensive arguments in the previous response that explain the conditions used in the Cook patents and the Sugano reference and the fact that Cook's conditions could actually be expected to produce more unwanted isomers. The Examiner has failed to compare the references and is requested to do so.

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<sup>5</sup> Office Action, page 3.

<sup>6</sup> *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989).

<sup>7</sup> *In re Dillon*, 919 F.2d 688, 696, 16 USPQ2d 1897, 1904 (Fed. Cir. 1990)(*en banc*), *cert. denied*, 111 S. Ct. 1682 (1991).

<sup>8</sup> Office Action, page 3.

With respect to reasonable expectation of success, the Examiner again merely relies on his previous arguments and summarily rejects the Applicants arguments without explanation and apparently without consideration of the record as a whole.

The Examiner states that "[t]he issue is: will a person with ordinary skill in the art be able to make such a composition, the issue is not whether Cook's disclosed method therein can make the claimed composition (in large scale)."<sup>9</sup> Applicants respectfully submit that Examiner has misstated the standard for expectation of success. Reasonable expectation of success occurs when "the prior art would have suggested to one of ordinary skill in the art that this process **should** be carried out and **would** have a reasonable likelihood of success, viewed in light of the prior art."<sup>10</sup> Accordingly, contrary to the Examiner's assertion, the prior art (*i.e.*, the references cited by the Examiner) must provide a reasonable expectation of success in producing the claimed compositions. Reasonable expectation of success is determined in the context of what is disclosed in the cited references. Since the cited references do not disclose a method suitable for making the claimed compositions, there can be no reasonable expectation of success. Therefore, Applicants respectfully submit that the Examiner's summary of the issue is not in accordance with patent law standards. Accordingly, the Examiner has not established a *prima facie* case of obviousness.

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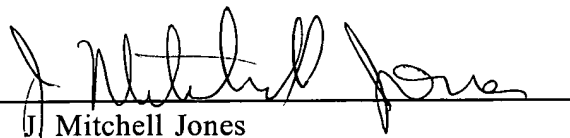
<sup>9</sup> Office Action, page 3.

<sup>10</sup> *In re Dow Chemical*, 5 USPQ2d 1529, at 1532 (Fed. Cir. 1988).

**Conclusion**

All grounds of rejection and objection of the Office Action of April 30, 2001 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: July 30, 2001

  
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**Appendix 1**

A clean version of the entire set of pending claims pursuant to 37 C.F.R. §1.121 (c)(3) as they would appear following entry of this amendment.

1. (Amended once) An animal feed comprising conjugated linoleic acid alkyl esters in a biologically active concentration, said alkyl esters comprising less than about two percent 8,10 and 11,13 octadecadienoic acid isomers.
2. The animal feed of claim 1 wherein the concentration of conjugated linoleic acid alkyl esters in said feed is about 0.05 to 3.5 percent by weight.
3. (Amended once) The animal feed of claim 1 wherein said conjugated linoleic acid alkyl ester is comprised of at least 50 percent up to about 99 percent by weight of octadecanoic acid alkyl ester isomers selected from the group consisting of c9,t11-octadecanoic acid alkyl ester and t10,c12-octadecanoic acid alkyl ester, with less than [5] about two percent of 11,13-octadecanoic acid alkyl ester.
4. (Amended twice) A conjugated linoleic acid alkyl ester composition for safe use as a feed, food ingredient, or food supplement obtained by direct isomerization of an unrefined linoleic acid comprising
  - a composition of isomers in one part comprising at least 50 percent by weight of ester isomers selected from the group consisting of c9,t11- octadecadienoic acid alkyl ester and t10,c12-octadecadienoic acid alkyl ester, and combinations thereof, and
  - in a second part comprising less than two percent by aggregate weight of ester isomers selected from the group consisting of 8,10-octadecadienoic acid alkyl esters, 11,13-octadecadienoic acid alkyl esters, and trans,trans-octadecadienoic acid alkyl esters, and
  - in a third part comprising in the range of 0.1 to 0.5 percent phosphatidyl residue remaining after isomerization of said unrefined linoleic acid.

5. The ester of claim 4 wherein said c9,t11-octadecanoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of octadecanoic acid alkyl esters.

6. The ester of claim 4 wherein said t10,c12-octadecanoic acid alkyl ester contained in said first composition part constitutes greater than 60 percent of the total isomers of octadecanoic acid alkyl esters.

7. (Amended once) A conjugated linoleic acid alkyl ester composition for use in domestic animal feed, food ingredients, or human dietary supplements made by the process comprising

providing an unrefined linoleic acid alkyl ester having phosphatidyl residue in the range of about 0.1 to about 0.5 percent

treating with an alkali alcoholate at low temperature in the presence of a monohydric low molecular weight alcohol to cause isomerization of at least 50 percent of the linoleic acid alkyl ester to conjugated linoleic alkyl ester at low temperature,

acidifying by addition of an aqueous acid, and

separating the linoleic conjugated linoleic acid alkyl ester from said aqueous acid without distillation.

8. The ester of claims 1-7 wherein said alkyl ester has an alkyl radical selected from the group consisting of methyl-, ethyl-, propyl-, isopropyl-, butyl-, and isobutyl-.